

### **REMARKS**

Claims 1-9, 11, and 13-17 are pending in the application. Claims 6-9 and 11 are withdrawn. Claims 1-9, 11 and 13-17 have been amended. Applicant reserves the right to pursue the original and new claims in this and other applications.

Claims 1-5 and 17 stand rejected under 35 U.S.C. §112, ¶ 1 for failing to comply with the written description requirement. The Office action asserts that the phrases “temperature independent” and “without regard to the temperature” lack support in the disclosure.

Although the specification does not use the term “temperature,” the specification does discuss in exemplary embodiments that the circulation-promoting means comprise “heatable elements” or “elements that can be heated by a direct supply of energy.” *See e.g.*, Published Application 2007/0167695 at ¶¶ [0017] – [0018], [0036] – [0038]. Accordingly, Applicant respectfully asserts that one of ordinary skill in the art would understand that a circulation promoting means that is temperature independent or a circulation promoting means that operates to enhance blood flow regardless of the temperature of the neutral electrode only include those embodiments which promote circulation without elements that are heated or can be heated. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Claims 1-5 and 17 stand rejected under 35 U.S.C. §112, ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Office Action asserts that the phrase “without regard to temperature” is vague as it is unclear what temperature is being referenced. Applicant has amended the term “without regard to the temperature” to “without regard to a temperature of the neutral electrode.” Accordingly, Applicant respectfully requests withdrawal of the rejection.

The present invention, as claimed, relates to an HF-generator having a neutral electrode. The neutral electrode has a circulation promoting means which is adapted to enhance blood flow/promote circulation. In some exemplary claimed embodiments of the invention, the blood flow is enhanced irrespective of the temperature. Specially, the circulation promoting means does

not have any elements which purposefully change temperature in order to promote blood flow. Instead, the circulation promoting elements promote blood flow without changing the temperature of the neutral electrode. The enhancement of blood flow reduces the contact resistance between the neutral electrode and the body.

Claims 1-5 and 13-17 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,505,715 to Shah et al. (hereinafter "Shah"). Applicant respectfully traverses the rejection.

Independent claim 1 recites an "HF-generator for high frequency (HF) surgery with a neutral electrode, the electrode comprising ... a temperature independent circulation-promoting means adapted to enhance blood flow, without regard to the temperature of the neutral electrode, at least through the portion of the patient's body in contact with said at least one electrically conductive section."

Independent claim 13 recites an "HF-generator for use in high frequency (HF) surgery with a neutral electrode, the electrode comprising: at least one electrically conductive section for contacting a patient's body, wherein the at least one electrically conductive section is coated with a gel containing a circulation promoting agent as a circulation promoting means adapted to enhance blood flow at least through said body portion in contact with said at least one electrically conductive section to reduce a contact resistance between said conductive section and said body portion."

Independent claim 16 recites an "HF-generator with a neutral electrode for use in high frequency (HF) surgery, the electrode comprising: at least one electrically conductive section for contacting a patient's body, wherein said section is coated with a conductive gel to improve the contact between said section and said portion of the patient's body and wherein said gel incorporates a substance that contains a circulation promoting agent as a circulation promoting means adapted to enhance blood flow at least through said body portion in contact with said at least one electrically conductive section."

Independent claim 17 recites an “HF-generator with a neutral electrode for high frequency (HF) surgery, the electrode comprising ... a circulation-promoting means adapted to enhance blood flow, without regard to the temperature of the neutral electrode, at least through the portion of the patient’s body in contact with said at least one electrically conductive section, wherein said circulation-promoting means comprises a substance that contains a circulation-promoting agent.”

As discussed in response to the previous Office Action, Shah relates to a system and method for non-invasively delivering deoxyspergualin (“DSG”) at a flux sufficient to achieve a therapeutic dose, especially in the suppression of immune activity. More particularly, the Shah invention relates to a device which can provide chronic and convenient out-patient administration of DSG. In one embodiment of Shah, an agent for reducing **skin irritation** may be included with the DSG (e.g., bisabolol, methyl nicotinate or capsaicin). Shah does not discuss using any circulation promoting agents nor does Shah identify capsaicin as a circulation promoting agent. The Office Action states that “[t]he reference discloses an electrode including a conductive section 20 coated with a gel containing capsaicin ... [c]apsaicin is disclosed at column 9, line 54.” However, the Office Action fails to assert or prove that Shah teaches that capsaicin is a circulation promoting agent. It is the PTO’s burden to prove non-patentability of the claims. In this case, the PTO has failed to provide any evidence that Shah teaches a circulation promoting means. *Ethicon v. Quigg*, 849 F.2d 1422, 1427, 7 U.S.P.Q.2d 1152, 1156 (Fed. Cir. 1988) (“The burden is on the PTO to show nonpatentability of the claimed subject matter by a preponderance of the evidence.”). Shah simply fails to disclose an HF-generator let alone an HF-generator having a neutral electrode for use in high frequency surgery and/or HF-generator with a neutral electrode having a circulation promoting means which is adapted to enhance blood flow/promote circulation and reduce contact resistance.

Accordingly, Shah does not teach an “HF-generator for high frequency (HF) surgery with a neutral electrode, the electrode comprising ... a temperature independent circulation-promoting means adapted to enhance blood flow, without regard to the temperature of the neutral electrode, at least through the portion of the patient’s body in contact with said at least one

electrically conductive section,” as recited in independent claim 1; an “HF-generator for use in high frequency (HF) surgery with a neutral electrode, the electrode comprising: at least one electrically conductive section for contacting a patient’s body, wherein the at least one electrically conductive section is coated with a gel containing a circulation promoting agent as a circulation promoting means adapted to enhance blood flow at least through said body portion in contact with said at least one electrically conductive section to reduce a contact resistance between said conductive section and said body portion,” as recited in independent claim 13; an “HF-generator with a neutral electrode for use in high frequency (HF) surgery, the electrode comprising: at least one electrically conductive section for contacting a patient’s body, wherein said section is coated with a conductive gel to improve the contact between said section and said portion of the patient’s body and wherein said gel incorporates a substance that contains a circulation promoting agent as a circulation promoting means adapted to enhance blood flow at least through said body portion in contact with said at least one electrically conductive section,” as recited in independent claim 16; and an “HF-generator with a neutral electrode for high frequency (HF) surgery, the electrode comprising ... a circulation-promoting means adapted to enhance blood flow, without regard to the temperature of the neutral electrode, at least through the portion of the patient’s body in contact with said at least one electrically conductive section, wherein said circulation-promoting means comprises a substance that contains a circulation-promoting agent,” as recited independent claim 17.

Claims 2-5 and 15 depend from claim 1 and are allowable for at least the reasons mentioned above, and claims 14 depends from claim 13 and is allowable for at least the reasons mentioned above. Applicant respectfully requests withdrawal of the rejection.

Claims 1, 3, 4 and 17 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,544,258 to Fleenor et al. (hereinafter “Fleenor”). Applicant respectfully traverses the rejection.

As discussed in the previous response, Fleenor relates to an improved return electrode. The problem Fleenor attempts to solve is the elimination of patient burns without the need for disposable electrodes and monitoring circuits. *See* Fleenor at col. 4, lines 21-27. One embodiment

of Fleenor, illustrated in FIG. 22 and discussed in detail starting at col. 27, line 13, relates to an electrode having a sleeve and pump assembly. The sleeve provides heating and cooling characteristics to the patient through the electrode. *Id.* at col 27, lines 20-29. An interior chamber of the electrode is filled with a material capable of being heated and/or cooled. The material is input into the interior chamber through an input end and output from an output end of the chamber. *Id.* at col. 27, lines 49-56. A pump is used to circulate material through the sleeve. However, Fleenor fails to teach increasing the circulation of the patient by a circulation promoting means that does not involve changing the temperature of a neutral electrode. Fleenor does not teach any means for increasing blood flow for which the temperature is irrelevant.

The Office Action, at 3, asserts that the label “temperature independent” preceding the means clause does not patently limit the function of the means. However, Applicant respectfully asserts that the “temperature independent” limitation of claim 1 describes the type of circulation promoting means that is claimed and thus, limits the types of circulation promoting means to those that do not change the temperature of the neutral electrode. In addition, claim 17 also limits the use type of circulation-promoting means to one that is “adapted to enhance blood flow, without regard to the temperature of the neutral electrode.” The circulation promoting means of claim 17 is likewise limited to only those that do not change the temperature of the neutral electrode.

Accordingly, Fleenor fails to disclose an “HF-generator for high frequency (HF) surgery with a neutral electrode, the electrode comprising ... a temperature independent circulation-promoting means adapted to enhance blood flow, without regard to the temperature of the neutral electrode, at least through the portion of the patient’s body in contact with said at least one electrically conductive section,” as recited in independent claim 1 and an “HF-generator with a neutral electrode for high frequency (HF) surgery, the electrode comprising ... a circulation-promoting means adapted to enhance blood flow, without regard to the temperature of the neutral electrode, at least through the portion of the patient’s body in contact with said at least one electrically conductive section, wherein said circulation-promoting means comprises a substance that contains a circulation-promoting agent,” as recited in independent claim 17. Claims 3 and 4

depend from claim 1 and are allowable for at least the reasons mentioned above. Applicant respectfully requests withdrawal of the rejection.

Claim 2 stands rejected under 35 U.S.C. § 103(a) as being obvious over Fleenor in view of U.S. Patent No. 4,387,714 to Geddes et al. (hereinafter "Geddes"). The rejection is respectfully traversed. Claim 2 depends from claim 1 and is allowable over Fleenor for at least the reasons mentioned above with respect to claim 1. Geddes fails to overcome the deficiencies of Fleenor. Accordingly, Applicant respectfully requests withdrawal of the rejection.

In view of the above, Applicant believes the pending application is in condition for allowance. Favorable action on the merits is earnestly solicited.

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